

### REMARKS/ARGUMENTS

The rejections presented in the Office Action dated June 5, 2006 (hereinafter Office Action) have been considered. Claims 1-20 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

With respect to the non-statutory obviousness-type double patenting rejections of Claims 1-20 based on U.S. Patent No. 6,704,590 to Haldeman, Applicant submits the attached Terminal Disclaimer Under 37 C.F.R. §1.321(c). This submission is believed to overcome both of the double patenting rejections; therefore, Applicant requests that each of the double patenting rejections be withdrawn.

Applicant respectfully traverses each of the §103(a) rejections based upon the teachings of U.S. Patent No. 6,514,249 to Maguire *et al.* (hereinafter “Maguire”) because Maguire does not correspond to the claimed invention. For example, Maguire does not teach at least detecting changes in blood flow turbulence based on sensed blood flow velocity signals, as claimed (*e.g.*, independent Claims 1, 11 and 18). The term “turbulence” is used only twice in Maguire and is not used in a manner that would indicate that the teachings of Maguire detect blood flow turbulence. The first instance of the term is merely to describe how ultrasonic sensors are used to determine velocity: ultrasonic sound waves are reflected back to a sensor where the reflections are typically caused by particles and turbulence in the blood flow. Column 43, lines 9-12. The second instance of the term is in a discussion of how a radiopaque dye is rapidly dispersed due to turbulence in an atrium of the heart. Column 44, lines 49-51.

Contrary to the Examiner’s assertion, Maguire does not teach that greater turbulence is expected within a cardiac chamber relative to a pulmonary vein; instead, Maguire teaches that a lesser velocity is expected: “blood has been observed to flow faster in the vein than in the atrium.” Column 7, lines 17-18. Maguire does not teach or suggest any detection of changes in blood flow turbulence, as claimed.

With particular respect to the Examiner's assertion that detection of changes in turbulence as reflected in velocity changes would have been inherent, Applicant traverses because the Examiner has not presented any of the requisite evidence for supporting such an assertion and such an assertion is not supported by the teachings of Maguire. Applicant notes that "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). MPEP §2112 further states that "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)."

As discussed above, Maguire is directed to ascertaining the position of a catheter by measuring the velocity of blood near the catheter (*see, e.g.*, column 7, lines 15-16) and makes no reference to using blood flow velocity to detect changes in blood flow turbulence. The Examiner has not shown or asserted that Maguire teaches using Doppler-sensed blood flow velocity data to determine any other parameters. Thus, the Examiner has not shown that Maguire teaches each of the claimed limitations, and the asserted limitations have not been shown to be inherent in Maguire.

Applicant further submits that Maguire does not teach "a detected change in blood flow turbulence [that] is indicative of a relative change in position of the flexible shaft's distal end between cardiac vessel and cardiac chamber locations." Since Maguire does not teach, expressly or inherently, detection of changes in blood flow turbulence, Maguire does not teach that such changes would be indicative of changes in the position of a guiding catheter. Without a presentation of correspondence to each of the claimed limitations, the

§103(a) rejections are improper and should not be maintained. Applicant accordingly requests that each of the rejections be withdrawn.

Dependent Claims 2-4, 6 and 8 depend from independent Claim 1, dependent Claims 12-17 depend from independent Claim 11, and dependent Claims 19 and 20 depend from independent Claim 18. Each of these dependent claims also stand rejected under 35 U.S.C. §103(a) as being unpatentable over the above-discussed Maguire reference. While Applicant does not acquiesce to any particular rejections to these dependent claims, including any assertions concerning descriptive material, obvious design choice and/or what may be otherwise well-known in the art, these rejections are moot in view of the remarks made in connection with independent Claims 1, 11 and 18. These dependent claims include all of the limitations of their respective base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. “If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.” MPEP §2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent Claims 2-4, 6, 8, 12-17, 19 and 20 are also allowable over Maguire.

Regarding the §103(a) rejection of dependent Claim 5 over Maguire in view of U.S. Patent No. 4,790,323 to Leavitt *et al.* (hereinafter “Leavitt”), Applicant traverses because the asserted references, alone or in combination, do not correspond to the claimed invention. As discussed above, Maguire fails to correspond to the limitations of independent Claim 1 (from which Claim 5 depends). The Examiner’s further reliance on Leavitt does not overcome the above-discussed deficiencies in Maguire because Leavitt does not teach detecting changes in blood flow turbulence, as claimed. Thus, the asserted combination of Maguire with Leavitt does not teach each of the claimed limitations of dependent Claim 5, and the rejection should be withdrawn.

In addition to having to show that the asserted combination of references teaches or suggests all of the claim limitations, the Examiner must show evidence of motivation to combine these references as asserted. Applicant respectfully submits that this requirement has not been met.

The requisite evidence of motivation to combine the cited references as asserted has not been presented, nor does such motivation exist based on the cited references. The Examiner merely asserts that it would have been well-known to assess a level of turbulence as taught by Leavitt because Maguire allegedly teaches that turbulence increases in a heart chamber relative to a vein. This is not evidence of motivation to combine Leavitt's assessment of turbulence with the teachings of Maguire but rather, is a generalized statement of what is asserted as being taught by Leavitt and Maguire. No evidence has been provided that a skilled artisan would have attempted to introduce the asserted manner of determining turbulence to the teachings of Maguire.

The examiner must show some objective teaching leading to the asserted combination. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). Since Maguire does not teach any detection of changes in blood flow turbulence, as discussed above, it is respectfully submitted that the teachings of Maguire and Leavitt would have provided insufficient guidance for a skilled artisan having these references before him/her to make the combination suggested by the Examiner. Applicant respectfully asserts that the Examiner's conclusion of obviousness is, instead, based on improper hindsight reasoning using knowledge gleaned only from Applicant's disclosure. As stated by the Federal Circuit:

Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight.

*In re Dembiczak*, 50 USPQ2d 1614, (Fed. Cir. 1999) (citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985)). Without a suggestion of the desirability of "the combination," a combination of such references is made in hindsight, and the "range of sources available, however, does not diminish the requirement for actual evidence." *Id.* It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown and that this evidence be "clear and particular." *Id.* Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence. *Id.*

As Maguire does not teach detecting changes in turbulence, Applicant respectfully submits that the asserted combination simply does not contemplate the proposed combination. This piecemeal selection of elements is tantamount to mixing teachings out of context. Such a rejection is not permissible under §103. *See In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000) (proposed modification must not be made in the abstract but rather made in view of the entire teaching of the prior art).

There is nothing in the references or what is in the ordinary skill in the art that would lead to combining the cited references as asserted – rather, the proffered motivation is made in hindsight. For at least the aforementioned reasons, Applicant respectfully submits that a case of *prima facie* obviousness has not been satisfied for lack of a presentation of evidence of motivation to combine the cited references. Applicant accordingly requests that the rejections be withdrawn.

Regarding the §103(a) rejection of dependent Claim 7 based on Maguire and further in view of U.S. Patent No. 4,920,967 to Cottonaro *et al.* (hereinafter “Cottonaro”), Applicant respectfully traverses. As discussed above, Maguire fails to correspond to the limitations of independent Claim 1 (from which Claim 7 depends). The Examiner’s further reliance on Cottonaro does not overcome the above-discussed deficiencies in the underlying combination as Cottonaro does not make any reference to turbulence or detection of changes therein. Thus, the asserted combination of Maguire with Cottonaro does not teach each of the claimed limitations of dependent Claim 7, and the rejection should be withdrawn.

Moreover, the requisite evidence of motivation to combine the Maguire and Cottonaro as asserted has not been presented, nor does such motivation exist based on the cited references. In the Office Action, the Examiner merely asserts that “it was well known to entertain a laser Doppler and detector pair as an alternative to piezocrystal Doppler detection.” Again, this is not evidence of motivation to combine the teachings of Cottonaro with those of Maguire but rather, it is a generalized statement of what is asserted as being taught by Cottonaro. No evidence has been in support of the asserted combination. Without a presentation of evidence that a skilled artisan would have combined the

references as asserted, the rejection is improper and should not be maintained. Applicant accordingly requests that the rejection be withdrawn.

Regarding the §103(a) rejection of dependent Claims 9 and 10 based on Maguire in view of U.S. Patent No.5,022,399 to Biegeleisen *et al.* (hereinafter “Biegeleisen”), Applicant respectfully traverses. As discussed above, Maguire fails to correspond to the limitations of independent Claim 1 (from which Claims 9 and 10 depend). The Examiner’s further reliance on Biegeleisen does not overcome the above-discussed deficiencies in the underlying combination as Biegeleisen does not make any reference to turbulence or detection of changes therein. Thus, the asserted combination of Maguire with Biegeleisen does not teach each of the claimed limitations of dependent Claims 9 and 10, and the rejection should be withdrawn.

Applicant further traverses the rejection because the Examiner has not presented any evidence from the cited references that a skilled artisan would have combined the references as asserted. The examiner must show some objective teaching leading to the asserted combination. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). No citations or evidence have been presented in support of modifying the pulmonary surgical device of Maguire with the non-surgical varicose vein treatment teachings of Biegeleisen. Thus, Applicant submits that the rejection is also improper for a failure to present the requisite evidence of motivation and accordingly requests that the rejection be withdrawn.

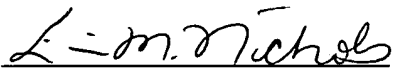
It should be noted that Applicant does not acquiesce to the Examiner’s statements or conclusions concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, common knowledge at the time of Applicant’s invention, officially noticed facts, and the like. Applicant reserves the right to address in detail the Examiner’s characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.023C1) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact her at the number below to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC  
8009 34<sup>th</sup> Avenue South, Suite 125  
Minneapolis, MN 55425  
952.854.2700

Date: October 5, 2006

By: 

Erin M. Nichols  
Reg. No. 57,125